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The Honorable Claire C. Cecchi  
United States District Court, District of New Jersey  
50 Walnut Street, Courtroom MLK 5B  
Newark, NJ 07101

Re: **Defendants' Letter Brief in Support of Disputed ESI Protocol Provisions**  
*In Re: Proton-Pump Inhibitor Products Liability Litigation (No. II)*  
Case No. 2:17-md-02789-CCC-MF

Dear Judge Cecchi:

Defendants respectfully submit the following letter brief in support of their proposed protocol to govern the production of documents and electronically stored information ("ESI") in this MDL. With this Court's guidance, Defendants have reached agreement with Plaintiffs on the ESI protocol on all but two outstanding issues: (1) whether redacted documents (which will be produced in TIFF-plus format) will be produced in black and white (subject to reasonable specific requests for production in color), and (2) whether the parties must take basic, simple steps to ensure the confidentiality and authenticity of documents provided in native format.

### **I. Production of Redacted Documents in Black & White.**

Plaintiffs request that Defendants produce all redacted file types in color if the original, unredacted version of the document exists in color. Given that the parties have already agreed to produce documents in native format, it naturally follows that unredacted documents will be produced in color by virtue of their native production. In the spirit of cooperation, Defendants are willing to honor reasonable requests for specific redacted documents to be reproduced in color. Plaintiffs however, reject Defendants' compromise, and instead demand that all redacted files shall also be produced in color if the original unredacted version was in color.

Notably, the ESI Order entered by Your Honor in May between Plaintiffs and AstraZeneca did not demand that redacted documents be produced in color, nor did the ESI Orders stipulated to by the parties in other jurisdictions. Rather, the Order states, "[E]ach Party may make reasonable requests, for good cause, for production of specifically identified Documents in color. The Parties shall confer whether cost shifting is appropriate."<sup>1</sup> Plaintiffs now seek to ignore this provision and impose an unreasonable and burdensome requirement on Defendants to produce any and all redacted file types in color. The AstraZeneca Defendants have

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<sup>1</sup> See Order Regarding the Format of Production of Hardcopy Documents and Electronically Stored Information, *Various Plaintiffs, et al. v. AstraZeneca Pharmaceuticals, LP, et al.* Case 2:16-cv-05143-CCC-MF (D.I. 35).



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already produced nearly 700,000 pages of documents, most of which are redacted, that may be impacted by Plaintiffs' about face.<sup>2</sup> Further, Defendants are preparing documents for production in response to Plaintiffs' discovery demands, which may also be impacted by the request for color production. Plaintiffs' position is prejudicial and should be denied.

To require Defendants at this stage to produce color copies of all redacted files is not only unreasonable, but also not supported by the law. As noted in Defendants' September 26, 2017, Letter to the Court, producing in black and white is in accord with multiple federal court opinions. *See, e.g., Clouser v. Golden Gate Nat'l Senior Care*, Civ. A. No. 3:15-33, 2016 WL 4223755, at \*6 (W.D. Pa. Aug. 9, 2016); *Dizdar v. State Farm Lloyds*, Civ. A. No. 7:14-cv-402, 2015 WL 12780640, at \*10, \*12 (S.D. Tex. Jan. 21, 2015) (granting defendants' request to produce documents in black and white); *Victor v. Varano*, Civ. No. 3:11-cv-891, 2012 WL 1514845, at \*7 (M.D. Pa. May 1, 2012) ("[W]e find no basis to compel Defendants to produce color photographs when they have already made black-and-white copies available.").

Plaintiffs' proposal imposes a disproportionate burden and expense on Defendants. As an initial matter, there is no programmatic way to search for and identify files that contain color. This means that in order to produce redacted files in color, Defendants will have to either: (1) individually review *each* redacted document to determine whether it contains color, and if so, convert the files to color images, or (2) convert *all* redacted documents to color images. Both options are inefficient and will increase the costs associated with review and discovery in this matter. Further, Plaintiffs' demand that all redacted files be produced in color will add significant expense to Defendants' already asymmetrical discovery obligations. In order to produce a redacted file in color, the document must be converted to color by imaging the file to a single page .JPG format. The file size of the resulting .JPG color image is an average of ten times larger than a black and white TIFF image, which translates into a significant increase in the monthly hosting costs associated with these documents that Defendants will bear through resolution of the litigation.

Considering the vast majority of documents to be produced by Defendants will be easily understood regardless of whether they are in color or black and white, Plaintiffs' proposal would force Defendants to incur substantial, unnecessary costs for what is likely to be few documents actually needed in color by Plaintiffs. *See Interfaith Cnty. Org. v. Honeywell Int'l, Inc.*, 426 F.3d 694, 717 (3d Cir. 2005), as amended (Nov. 10, 2005) ("obviously color copies are more expensive than black and white ones"). Plaintiffs' approach is patently unreasonable and inefficient. Defendants' proposal, on the other hand, provides a reasonable solution in which Defendants are not burdened with unnecessary costs, but still allows for Plaintiffs to obtain documents in color when they believe color is necessary to understand a document's meaning.

Plaintiffs argue that they should not be required to cooperate so far as to make requests for specific redacted documents in color because Defendants will then know which documents are of

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<sup>2</sup> Documents produced to date include clinical trial materials and reports of adverse events to FDA, which often contain voluntary reporter and patient identifying information. Federal regulations and privacy laws require companies to redact such information.



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interest, therefore giving Defendants a competitive advantage. Instead, Plaintiffs demand that all redacted items with any color content be produced in color with redactions. This argument is a red herring. Because Defendants have agreed to produce documents in Plaintiffs' preferred native format, it is unlikely that the redacted documents Plaintiffs seek in color will be central to the claims of this litigation. Moreover, Plaintiffs' demand for production of documents in color is the exception to the standard practice in pharmaceutical products liability MDLs that redacted documents be produced in black and white TIFF images.<sup>3</sup> Plaintiffs have stipulated to and

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<sup>3</sup> See Pretrial Order No. 49, Electronically Stored Information Protocol, *In Re: Taxotere (Docetaxel) Prods. Liab. Litig.*, MDL No. 2740, 2:16-md-02740-KDE-MBN (E.D. La. July 6, 2017) (D.I. 611, 611-1) ("All non-database ESI shall be produced in TIFF format. All TIFF formatted documents will be single page, black and white, Group 4 TIFF at 300 X 300 dpi resolution and 8½ X 11 inch page size, except for documents requiring different resolution or page size."); Case Management Order No. 16, Order Regarding Electronically Stored Information, *In Re: Invokana (Canagliflozin) Prods. Liab. Litig.*, MDL No. 2750, 3:16-md-2750-BRM-LHG (D.N.J. June 7, 2017) (D.I. 172) ("The parties shall produce [ESI] in reasonably usable form. Except for documents produced in native format as agreed herein or as agreed hereafter by the parties, such reasonably usable form shall be the single-page [black and white] TIFF image format. . . . Each Party may make requests, for good cause, for production of specifically identified documents in color."); CMO No. 3: Order Establishing Protocol for Electronically Stored Information, *In re: Eliquis (Apixaban) Prods. Liab. Litig.*, MDL No. 2754, 1:17-md-02754-DLC (S.D.N.Y. Apr. 17, 2017) (D.I. 32) ("Unless otherwise specified herein, a Producing Party shall produce electronic documents in black-and-white, single page, 300 DPI, Group IV\* tagged image file format ("TIFF") images . . . A producing party . . . shall accommodate reasonable requests for production of specific images in color . . ."); *Warner v. Bristol-Myers Squibb*, MDL No. 2776, 1:16-cv-08187 LGS (S.D.N.Y. Mar. 15, 2017) (D.I. 36) ("Defendants will provide its productions in TIFF formant, with the exception of Excel documents, which will be redacted natively and produced in native form. All TIFF Documents will be black and white, single page, 300 DPI, Group IV TIFF formant."); Consent Order Regarding the Format of Production of Hardcopy Documents and Electronically Stored Information, *In re: Fluoroquinolone Prods. Liab. Litig.*, MDL No. 2642, 0:15-md-02642-JRT (D. Minn. May 18, 2016) (D.I. 176) ("After such redactions, the Producing Party either shall produce the redacted file in TIFF format, with extracted or OCR text files and the associated metadata set out in Attachment A or shall produce the redacted copy in native format" and any party may "make reasonable requests, for good cause, for production of specifically identified documents in color."); Stipulated Order Re: Discovery of Electronically Stored Information, *In re: Viagra (Sildenafil Citrate) Prods. Liab. Litig.*, MDL No. 2691, 3:16-md-02691-RS (N.D. Cal. Oct. 25, 2016) (D.I. 120) ("Unless otherwise specified . . . the Parties shall produce all documents in black-and-white, single page, 300 DPI, tagged image file format ("TIFF") images, . . . Parties shall honor reasonable and specific requests for the production of documents as color images."); Corrected Case Management Order No. 15, Protocol for Electronically Stored Information (ESI) Production Format, *In Re: Testosterone Replacement Therapy Prods. Liab. Litig.*, MDL No. 2545, 1:14-cv-01748 (N.D. Ill. Nov. 6, 2014) (D.I. 469) ("Defendants shall produce other ESI (e.g., emails, word processing files, and presentation files) in .tif format. ESI shall be produced in black-and-white, single page, 300 DPI, Group IV\*.tif images with affiliated metadata as identified below. The Parties will accommodate reasonable requests for production of specific images in color."); Pretrial Order No. 20, Consent Order Regarding the Format for Production of Hardcopy Documents and Electronically Stored Information, *In Re: Xarelto (Rivaroxaban) Prods. Liab. Litig.*, MDL No. 2592, 2:14-md-02592 (E.D. La. June 15, 2015) (D.I. 1007) ("Documents produced in \*.tif image format will be single page black and white \*.tif files at 300 DPI, Group IV compression . . . Each Party may make requests, for good cause, for production of specifically identified documents in color."); Order Regarding ESI Agreement Governing Production of Documents Between Plaintiffs and AstraZeneca, *In Re: Nexium (Esomeprazole) Prods. Liab. Litig.*, MDL No. 2404, 2:12-ml-02404-DSF (C.D. Cal. Apr. 19, 2013, Mar. 28, 2013) (D.I. 126, 97-1) ("AstraZeneca will provide its productions . . . in [black and white] TIFF format for all hard copy, paper documents and for any document for which redaction is required with the exception of Excel documents, which will be redacted natively and produced in native form."); CMO No. 13 Governing the Format of Production, *In Re Yasmin and Yaz (Drospirenone) Mktg., Sales Practices and Prods. Liab. Litig.*, MDL No. 2100, 3:09-md-02100-DRH-PMF (S.D. Ill. Mar. 3, 2010) (D.I. 837) ("All production document images, whether scanned from hard



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followed the very protocol suggested by Defendants – and even agreed to such terms in this litigation until now – in numerous other MDLs without their key litigation strategy being divulged as a result of specific requests for reproduction of documents in color.

Defendants' proposal is an accepted, reasonable and proportionate approach aligned with the objectives of the Federal Rules, whereby Defendants will produce redacted documents in black and white in the first instance but, upon a showing of good cause by Plaintiffs, will meet and confer to discuss production of specified documents in color.

However, should Defendants be required to produce redacted files in color, Defendants respectfully request that Plaintiffs be ordered to bear the costs associated with production and hosting of such files. Pursuant to amended Federal Rule 26(b)(2), cost shifting is appropriate where discovery is disproportionate or unduly burdensome. *See The Sedona Conference Principles, Third Edition: Best Practices, Recommendations & Principles for Addressing Electronic Document Production*, 19 SEDONA CONF. J. 1, 48 (2017) (noting that Principle 13 was updated in 2017 “to reflect the amended Federal Rules’ treatment of cost allocation and its interplay with the proportionality analysis under amended Rule 26(b)(1).”); *The Sedona Conference Commentary on Proportionality in Electronic Discovery*, 18 SEDONA CONF. J. 141, 162 n.32 (2017) (“An alternative to limiting burdensome or expensive discovery is to shift its cost to the requesting party.”); *Oxbow Carbon & Minerals LLC v. Union Pac. R.R. Co.*, Case No. 11-cv-1049, 2017 WL 4011136, at \*7 (D.D.C. Sept. 11, 2017) (“[T]he Court may shift a portion of the costs to the requesting party in the event that the discovery request would unduly burden the producing party.”) (internal quotations omitted). Here, Defendants will be producing millions of pages of documents in Plaintiffs’ preferred native format. The majority of documents will be produced unredacted in color. For redacted documents, conversion to color images will increase Defendants’ hosting expense through the pendency of the litigation. Defendants should not be required to incur the additional expense attendant to a color production when the content and context of the majority of the redacted files will be readily apparent on the face of black and white images. Therefore, should the Court be inclined to order production of the redacted files in color, Defendants respectfully request that Plaintiffs bear the costs associated with production and hosting of the color images.

## II. Use of Documents Produced in Native Format.

Plaintiffs successfully argued for the production of certain file types, namely Word, PDF, and PowerPoint, in native format. At the October 11 hearing, this Court directed the parties to meet and confer about the parameters of that production, including “whether the Defendants ... would be amenable to doing a production in native as well as TIFF.” Transcript of Oct. 11, 2017 Hearing at 7:10-13. After further discussions, most Defendants agreed to produce the disputed file types in both native and TIFF-plus format (others may elect to produce solely in native). The

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copy documents or generated from native electronic documents, shall be provided as single-page Tagged Image File Format (‘.tiff format’) . . . If an original document contains color, the Defendants shall not deny reasonable requests for color copies of the original.”).



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native production satisfies this Court's Order, and the option of also providing certain documents in TIFF-plus will provide Defendants, who avail themselves of that option, an additional layer of uniformity and security.<sup>4</sup>

Recognizing the complexities of using native files as exhibits at depositions and at trial, this Court further directed the parties to "engage in a conversation regarding how documents would be used at depositions." *Id.* at 7:14-16. As detailed below, Defendants offer a number of practical, simple solutions to address their concerns over the security and authenticity of files produced in native format.

First, Defendants propose that if a Receiving Party wishes to print an item from its native file format, it must include the filename provided by the Producing Party on each page of the printed image. That filename, which will have a unique identifying number and the confidentiality designation for the item (if any), can be inserted automatically into the footer of each page of an item when printed; Plaintiffs will not have to type the filename manually. As a result, Defendants' proposed requirement will result in virtually no additional burden on the Receiving Party, while protecting the Defendants' very legitimate interests in their confidential information and prevent that information from being shared inadvertently with their competitors.

Second, where Defendants provide an item in native file format *and* a complete TIFF-plus image, and Plaintiffs wish to use the item as an exhibit at deposition or trial, Defendants propose that Plaintiffs should bring to the deposition one printed copy of the complete TIFF-plus image of any native file. This will allow the parties to compare – in real time, while a witness is asked to testify regarding a document – the printed native file with the TIFF-plus image. If the two printed images are substantively identical (which the parties expect will be the case the vast majority of the time), the examination will proceed unimpeded, and Defendants' concerns about potential discrepancies will be put immediately to rest.

During meet and confer discussions, Plaintiffs raised two concerns. First, they were concerned that this authentication process will interfere with the deposition. To address that concern, Defendants propose a reasonable solution: that the parties shall meet and confer if there are any differences, and that any time spent comparing the documents or discussing any differences shall not count against the examination time of the party wishing to use the native file. ESI Order, B.4.b.2. Second, Plaintiffs expressed concern about the burden and environmental impact of having to make double the number of copies of any potential exhibit if they wished to use native format documents. That is why Defendants have proposed that Plaintiffs bring only one copy – for counsel for the Producing Party – which presumably could be added to the record as an exhibit after the deposition if any discrepancies arose.

Defendants believe these two minor, simple safeguards will address most of their concerns about native production without imposing an undue burden on Plaintiffs, and request

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<sup>4</sup> Plaintiffs' proposal contemplates that slipsheets be created as placeholders for native files even where the corresponding TIFF-plus image (Bates-numbered document images) are produced. It is not technically feasible to provide a native, TIFF image, and slipsheet for the same document. To try to resolve this area of dispute, Defendants have pointed out that the first page of the TIFF image version is a suitable "slipsheet" substitute.



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that the Court adopt them in light of the Court's decision to require Defendants to provide the disputed file types in native format.

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